UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,335	04/09/2004	Paul D. Wightman	58562US005	9992

32692 7590 04/26/2007

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
DESAI, RITA J	
ART UNIT	PAPER NUMBER
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	10/821,335	WIGHTMAN ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *10,15-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/07 has been entered.

The claims pending in the elected group are 1-9, 11-14.

The rejection of claims 1-9, 11-14 under 35 USC 102(b) over US 4,689,338 Gerster et al still stands.

The applicants have amended the claims to insert via a linkage that comprises a covalent bond or a high-affinity non covalent interaction.

In the specifications the definition of comprises is not limiting. See page 6 lines 28-29.

"The term "comprises" and variations thereof do not have a limiting meaning where these terms appear in the description and claims, "

The rejection is being repeated here.

The claims 1-9 and 11-14 still stand rejected under 35 USC 102(b).

Applicants arguments are not fully convincing. The prior art does disclose the polyethelene macro-molecules formulation. These could be bonded to the reactive groups on the IRM molecules. Could be H bonding too.

Applicants specifications on page 21, lines 19-21 cleacly states that the IRM compound can be blended or mixed in. See below.

> IRM can be released and function in that manner. That is, for example, the IRM can be simply dissolved or blended into a macromolecular support material (e.g., as in a polymeric coating). Mixtures of the two types can also be used where desirable.

Applicants in their specification have not shown how the bonding takes place on the support. It just states it could be covalently bonded.

Hence the rejection still stands.

Applicants arguments are not persuasive. Applicants argue that theirs has a covalent bond, but he specification teacher that it just needs to be a strong bond.

The reference teaches the polyethylene glycol same as that given in applicants description of a macromolecular support material.

Also applicants specifications clearly teaches that the compound is attached by a sufficiently strong bond (H bonding is sufficiently strong) which may sometimes be covalently bonded.

During "formulation " drugs can get attached to the carrier via bonding.

Also see page 27 of the specification which clearly teaches that it can be just a hydrogen bonding which reads on formulation.

" Attachment to Substrates :

IRMs can be attached to a macromolecular support material through either

covalent attachment or non-covalent attachment. Non-covalent attachment of an IRM to a macromolecular support material includes attachment by ionic interaction or hydrogen bonding, for example."

In view of the lack of the scope of enablement the above rejection still stands.

Applicants claims are drawn to a support complex not a method of using it.

The rejection of claims 1-9 and 11 under 35 U.S.C. 112 first paragraph scope of enablement still stands. Again applicants claims are drawn to a complex itself, not to a method of using them. Thus the complex as such should be clearly enabled.

Claim 3 is drawn to a gel, foam, fiber, a hydrogel, a bead.

Thus it is clear that the compound is not dissolved or blended.

It is unclear how it can be covalently bonded. The location of the site of the covalent bond on a bead will be different than that on a gel. Applicants have not described the type of attachments and bonding.

Regarding applicants arguments regarding :-

Breadth of the claims :- Applicants arguments that they cover a broad variety of known substrates may be correct, however applicants have not show the active sites of where the reaction takes place and where the covalent bonding occurs, if covalent bonding is what applicants claims. Applicants description of the support material is

"Typically, the macromolecular support material is in the form of a solid (i.e., a solid support such as particles, fibers, membranes, films), but can also be in the form of

a polymeric gel, sponge, or foam, for example. A macromolecular support material can be made of a variety of materials, including substrates made of ceramic, glassy, metallic, or polymeric materials, or combinations of materials. The terms "substrate," "support material," or "support," may also be used herein to refer to a macromolecular support material. "

Glassy and ceramic compounds are not known to easily for a covalent bond with compounds.

The nature of the invention : applicants have not supported the fact that supports , generally to form complexes are known. Applicants support materials include compounds that do not form a covalent bond by itself. Thus with little known , applicants need to provide more as to how and where are the covalent bonds formed between the compound and the substrate to form a "complex".

Also on page 8 the specifications state

"In an IRM-support complex an IRM is attached to a macromolecular support material. As used

herein, the term "attached" includes both covalent bonding and non-covalent chemical

association (e.g., ionic bonding and hydrogen bonding) of an immune response modifier with a

macromolecular support material."

State of the art:- Applicants agree that the state of the art does not teach the complexes.

Level of predictability; even though the level of skill in the art is high , there is no predictability that compounds would form complexes with glass. Applicants have not

shown how these complexes are formed. Again applicants specification clearly states it can be ionic or a Hydrogen bonding . Does not have to be covalently bonded.

If it is so, as required by claim 2, applicants have not enabled where the site and location and between the compound and the substrate is.

Thus applicants have not provided proper direction as to the formation and enablement of the complex.

There is an undue amount of experimentation to make the invention of the applicants.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that,

> based on the evidence regarding each of the above factors, the specification, at the time the application was flied, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Applicants arguments:-

Applicants argue that their claims are enabled and have cited US6582,938 column 9 lines 24-33.

However the reference at column 9, lines 24-33 reads

expressly incorporated herein by reference. A nucleic acid probe array preferably comprises nucleic acids bound to a substrate in known locations. In other embodiments, the system may include a solid support or substrate, such as a membrane, filter, microscope slide, microwell, sample tube, bead, bead array, or the like. The solid support may be made of various materials, including paper, cellulose, gel, nylon, polystyrene, polycarbonate, plastics, glass, ceramic, stainless steel, or the like including any other support cited in U.S. Pat. No. 5,744,305 or U.S. Pat. No. 6,040,193. The solid support may preferably have a rigid or semi-rigid surface, and may preferably be spherical (e.g., bead) or substantially planar (e.g., flat surface) with appropriate wells, raised regions, etched trenches, or the like. The solid support may also include a gel or matrix in which nucleic acids may be embedded. The gene expression monitoring

Please note that in line 26 the reference describes a different embodiment, wherein the system may include a solid support. The solid support may also include a gel or a matrix in which the nucleic acid is embedded.

In column 18 of the US 2002/0022721 or US 6887665 it clearly states that the glass or pyrex is coated with a variety of material so that bonding can take place.

In preferred embodiments, the substrate is conventional glass, pyrex, quartz, any one of a variety of polymeric materials, or the like. Of course, the substrate may be made from any one of a variety of materials such as silicon, polystyrene, polycarbonate, or the like. In operation, the surface of the substrate is appropriately treated by cleaning with, for example, organic solvents, methylene chloride, DMF, ethyl alcohol, or the like. Optionally, the substrate may be provided with appropriate linker molecules on the surface thereof. The linker molecules may be, for example, aryl acetylene, ethylene glycol oligomers containing from 2–10 monomers or more, diamines, diacids, amino acids, or combinations thereof. In some embodiments the surface may be silanated. Thereafter, the surface is provided with protected surface active groups such as tertbutyloxycarbonyl (TBOC) or fluorenylmethoxycarbonyl (FMOC) protected amino acids. Such techniques are well known to those of skill in the art.

Thus for applicants to say that thus it is covalently bonded or strongly bonded is enabled is incorrect. The reference does not claim that these are covalently or strongly bonded to the solid support.

Thus applicants arguments are not convincing.

The rejection still stands.

New rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 –9, 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the claims to include "a high affinity non-covalent interaction".

The specifications on page 8 line 23 has high affinity only drawn to protein-ligand interaction.

The specifications has no description of the protein –ligand interaction. And only high affinity interaction is of a broader scope because it could include other interactions also.

The specification also does not have any description of the protein ligand interaction and which proteins and ligands are involved.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,030,129 Miller et al.

The reference discloses the same IRM compound with the gel, paste and so on.

These are all the solid support , with the compounds forming an IRM-Support complex.

In view of the lack of disclosure and enablement of the specific bonding that forms the complex the reference clearly anticipates the invention.

Claims 1-9, 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6894060 Slade.

See column 5, lines 47 and 48 which discloses the 5% cream of imiquimod.

In view of the lack of disclosure and enablement of the specific bonding that forms the complex the reference clearly anticipates the invention.

Conclusion

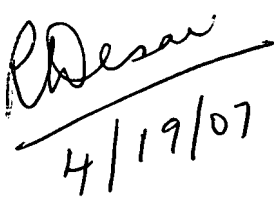
Claims 1-9, 11-14 still stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625



R.D.
April 17, 2007